

### **REMARKS**

Reconsideration of the subject application in view of the preceding amendments and the following remarks is respectfully requested.

Claim 1-6 are pending in this application. In this amendment, Claim 1 has been amended and Claims 2-6 have been added. No new matter has been added to the subject application by this amendment, nor have any new issues been raised.

Applicant reserves the right to pursue patent protection for claims of varying scope directed to any subject matter cancelled by this amendment, or other subject matter contained in the instant application, in any application filed hereafter which claims priority of the instant application.

### **The Office Action dated August 11, 2004**

In the outstanding Office Action, the Examiner indicated that the instant specification does not provided specific reference to parent applications.

Claim 1 stands rejected under 35 U.S.C. §102(b) as being purportedly anticipated by U.S. Patent No. 4,873, 992 to Bayne (hereinafter referred to as "Bayne"). Claim 1 was also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,740,049 and claim 1, of U.S. Patent No. 6,387,058.

### **Response by Applicant**

Applicant respectfully traverses the Examiner's rejections primarily because of the reasons set forth herein below. In summary, Applicant's claim includes elements which are neither disclosed nor suggested by the cited reference. Nevertheless, Applicant has amended the claim to address the aforementioned objections and particularly point out and distinctly claim subject matter disclosed by the Applicant with greater clarity. Applicant submits that the amended claim and new claims include elements which are neither disclosed nor suggested by the cited reference. To illustrate the position of the Applicant, the discussion herein addresses the outstanding rejections as if these same rejections were asserted against the amended set of claims presented herein.

#### **Priority**

Applicant has amended the specification to include reference to patent applications which are related to the instant application and the status of those applications. Thus, it is respectfully submitted that Applicant has now complied with all of the conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §120.

#### **102 Rejection based on Bayne**

The 102 rejection of the instant application based on Bayne is hereby traversed.

Bayne discloses a device for simultaneously collecting cytology cell samples from the endocervix and exocervix. The Examiner points to the embodiment depicted in Fig. 3 of Bayne as anticipating the present invention as now claimed. Bayne discloses a brush 40 which includes an exocervical brush portion 42 and an endocervical brush portion 44.

Exocervical brush portion 42 is provided with a "hollow shaft 46 which is sized and configured to telescope over the shaft of the endocervical bush portion 44" to "enable the shafts to rotate together when rotated by an attending physician." (Bayne, Col. 5, lins. 50-66). Brush portion 42 is provided with a disc 48 which in turn is provided with bristles 50. (Bayne, Col. 6, lines 5-9). Bayne describes bristles 50 as being long enough to enable the brushing surface to conform to the surface of the exocervix, even an irregularly shaped exocervix," among other things. (Bayne, Col. 6, lins. 10-13). It is described in Bayne that the attending physician inserts the brush into the vaginal cavity until the endocervical brush portion is located within the endocervical canal and the brushing surface of disc 48 is positioned against the patient's exocervix. The brush is then rotated one or two times to scrape cell samples from the respective endocervix and exocervix. (Bayne, Col. 6, lins. 14-22).

As described in the instant application at page 5, lines 7-12, among the advantages of the claimed invention is that a representative sample of cervical tissue can be obtained by a person through self-sampling because the mop-like sampling member does not need to be located precisely in relation to the cervix to obtain a representative sample. The sampling device described in Bayne does not recognize the problem of sampling devices that must be precisely placed in relation to the cervix to obtain a sample, much less teach a solution to this problem. Rather, Bayne, in the embodiment referred to by the Examiner, describes a sampling device consisting of two separate brushes, which must be engaged with each other, each having bristles of varying length shaped to correspond with the shape of a certain part of the cervix (*i.e.*, either the endocervix or the exocervix). The brush

claimed by Applicant may be used to sample cervical tissues of the endocervix and exocervix, whereas the brush portion 42 cited by the Examiner, by its configuration, can collect samples only from the exocervix.

Clearly, Bayne requires that its sampling device be placed in a precise location within the vaginal cavity, and that the sampling be performed by a physician or other health care professional. In addition, Bayne refers to cell samples as being "scraped," suggesting hardened bristles and that Bayne does not recognize another of the problems addressed by Applicant. The present invention claims a solution to the discomfort of such scraping action by providing, among other things, bristles which are sufficiently long and flexible to increase the softness and form a mop-like brush, as disclosed throughout the instant application, and in particular, on pages 7-8.

Thus, in contrast to Bayne, Applicant claims in amended independent Claim 1, "a device for obtaining a sample from a body cavity" which includes a "plurality of elongated flexible bristles of approximately uniform length," the bristles "defining opposing first and second bristle end portions," wherein the plurality of elongated flexible bristles are supported "in a direction substantially parallel to the longitudinal axis of the elongated portion to form a mop-like sample collecting member," among other things.

In independent Claim 5, Applicant claims "a brush for self-sampling of cervical tissue" which includes "a plurality of bristles of approximately uniform length," wherein "each bristle of the plurality of bristles has a modulus of elasticity to form a mop-like sampling head having a soft surface area sufficient to acquire a sample of cervical tissue," among other things.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the... claim. Richardson v. Suzuki Motor Co., 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Accordingly, it is respectfully submitted that the 102 rejection of Claim 1 based on Bayne should be withdrawn because, among other things, Bayne does not teach, describe or show elements now claimed by the present invention in as complete detail. Namely, Bayne does not teach, describe or show a "device for obtaining a sample from a body cavity" which includes "a plurality of elongated flexible bristles of approximately uniform length defining opposing first and second bristle end portions," wherein the plurality of elongated flexible bristles are supported "in a direction substantially parallel to the longitudinal axis of the elongated portion to form a mop-like sample collecting member," among other things, as now claimed by Applicant in Claim 1.

Furthermore, Bayne does not teach, describe or show "a brush for self-sampling of cervical tissue" which includes "a plurality of bristles of approximately uniform length," wherein "each bristle of the plurality of bristles has a modulus of elasticity to form a mop-like sampling member having a soft surface area sufficient to acquire a sample of cervical tissue," among other things, as now claimed by Applicant in Claim 5.

### **Conclusion**

Applicants believe that the amendment to the specification contained herein (namely the inclusion of a reference to related applications and their status), places the instant application in compliance with all conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §120.

Amended Claim 1 contains limitations which are not taught or suggested by Bayne. Thus, this claim is not anticipated by Bayne. Since independent Claim 1 and new independent Claim 5 contain limitations which are neither taught nor suggested by Bayne, the claims that depend from these claims, namely Claims 2-4 and 6, provide further limitations thereto, are also not anticipated by Bayne.

A terminal disclaimer filed concurrently herewith. Accordingly, it is respectfully submitted that as a result of this filing, all of the claims presently pending in this application are in condition for allowance, and such action is earnestly solicited.

If the Examiner believes that a personal or telephonic interview may facilitate resolution of any remaining matters, Applicant's representative may be contacted at the number indicated below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Richard H. Newman', is written over a horizontal line.

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